

residue and adding to said medium at least one of histidine, methionine or glycine in an amount effective to reduce said byproduct formation.

Claim 10 (previously presented): A method for producing a polypeptide comprising a serine residue comprising culturing transformed host cells in a medium and adding at least one of histidine, methionine or glycine to the medium in an amount effective to reduce formation of a byproduct polypeptide comprising an O-acetylserine residue in place of a serine residue.

Claim 11 (previously presented): A culture medium comprising:

- (i) a host cell transformed to recombinantly express a polypeptide comprising a serine residue;
- (ii) at least one of histidine, methionine or glycine added to the medium in an amount effective to reduce formation of a byproduct polypeptide comprising O-acetylserine residue in place of a serine residue.

REMARKS

Claims 3-11 remain pending in this application. Applicants respectfully request consideration of the below remarks.

Rejections under 35 U.S.C. § 112, second paragraph

The Office Action states that claims 3-11 are rejected, under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Office Action states that claims 3-11 are indefinite as the claims recite “in an amount effective” but do not indicate what is the effective amount. Applicants respectfully traverse these rejections.

Applicants respectfully submit that one of skill in the art would recognize the metes and bounds recited by the phrase “in an amount effective.” This phrase is commonly used and understood by those of skill in the art. Accordingly, Applicants respectfully submit that the phrase “in an amount effective” is suitably defined and would be recognized by one of skill in the art as corresponding to its common and understood definition and usage.

Further, Applicants respectfully submit that the phrase “in an amount effective” is described and defined in the specification. For example, the specification states, at page 8, line 16, that:

The amino acids can be added in an amount that inhibits biosynthesis of the amino acids added (glycine, histidine and/or methionine) in host cells during cultivation. For example, they can be appropriately added to prevent any lack of the amino acid content in the medium monitored during cultivation. Alternatively, the amino acids can be initially added to the medium in an amount sufficient to maintain a necessary amino acid level even at the end of cultivation, after the necessary amino acid level has been preliminarily calculated from the amino acid composition of the host cell (see Frederick C. H. et al., Chemical Composition of Escherichia coli in Escherichia coli and Salmonella, second edition, ASM press, pp. 13-16), the cell density obtained, the amino acid composition of the protein to be expressed and the expression level.

From at least this example, one of skill in the art would recognize that the metes and bounds of “in an amount effective” are those in which: (1) “they [(i.e., amino acids)] can be appropriately added to prevent any lack of the amino acid content in the medium monitored during cultivation;” and/or (2) “the necessary amino acid level has been preliminarily calculated from the amino acid composition of the host cell . . . , the cell density obtained, the amino acid composition of the protein to be expressed and the expression level.”

For at least the foregoing reasons, Applicants respectfully traverse the rejections of claims 3-11, under 35 U.S.C. § 112, second paragraph, and request their removal from the application.

Rejections under 35 U.S.C. § 102(b)

The Office Action states that claims 3-11 are rejected, under 35 U.S.C. § 102(b), as allegedly being anticipated by U.S. Patent No. 5,670,340, issued to Yabuta et al. (“Yabuta”). Applicants

respectfully submit that Yabuta fails to anticipate the invention, as recited by claims 3-11 of the present invention, as Yabuta does not disclose all of the elements and limitations of claims 3-11.

Claims 3-11 recite, *inter alia*, an element comprising the reduction of formation of a byproduct comprising an O-acetylserine residue. Claim 9 recites “A method for reducing formation of a byproduct polypeptide comprising an O-acetylserine residue” Claim 10 recites “A method for producing a polypeptide comprising . . . [reducing] formation of a byproduct polypeptide comprising an O-acetylserine residue” And claim 11 recites “A culture medium comprising . . . an amount effective to reduce formation of a byproduct polypeptide comprising O-acetylserine residue” Claim 3-8 are variously dependent on claims 9-11 and, thereby, likewise comprise the element of reduction of formation of a byproduct comprising an O-acetylserine residue. Applicants respectfully submit that Yabuta does not disclose or teach an O-acetylserine residue, much less a reduction in formation of a byproduct polypeptide of an O-acetylserine residue.

For at least the foregoing reasons, Applicants respectfully submit that Yabuta fails to anticipate claims 3-11, under 35 U.S.C. § 102(b), and respectfully request removal of these rejections from the application.

The Office Action states that claims 3-6 and 9-11 are rejected, under 35 U.S.C. § 102(b), as allegedly being anticipated by U.S. Patent No. 5,169,772, issued to Zimmerman et al. (“Zimmerman”). Applicants respectfully submit that Zimmerman fails to anticipate all of the elements and limitations of the present invention as recited in claims 3-6 and 9-11.

As discussed above with regard to Yabuta, claims 3-6 and 9-11, *inter alia*, recite as an element of reducing formation of a byproduct polypeptide comprising an O-acetylserine residue. Applicants respectfully submit that Zimmerman does not disclose or teach an O-acetylserine residue or the reduction of the formation of a byproduct polypeptide thereof.

For at least the foregoing reasons, Applicants respectfully submit that Yabuta fails to anticipate claims 3-6 and 9-11, under 35 U.S.C. § 102(b), and respectfully request removal of these rejections from the application.

CONCLUSION

Applicants respectfully request consideration of the above remarks. In view of the above remarks, early notification of a favorable consideration is respectfully requested. The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

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By: _____

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